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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/665,718

09/22/2003

R. Stephen Brown

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12/14/2007

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EXAMINER

BOWERS, NATHAN ANDREW

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

12/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/665,718

Applicant(s)

BROWN ET AL.

Examiner

Nathan A. Bowers

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-35 and 54-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-35 and 54-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 24, 25, 28-35 and 54-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bentsen (US 6566508) in view of Ukrainczyk (US 20040047535) and Applicant's admitted prior art.

With respect to claims 24 and 54-57, Bentsen discloses a system for detecting the presence of microorganisms. The system includes a vessel in which the microorganisms in the sample are incubated. Enzymes produced by the microorganisms are allowed to react with at least one substrate in order to produce a biological molecule. An excitation light source is provided for irradiating the biological molecule, and a detector is used to detect any subsequent fluorescence from the biological molecule. The detected fluorescence is indicative of the presence of microorganisms in the sample. This is disclosed in column 2, line 54 to column 3, line 22 and column 16, line 11 to column 19, line 18. Column 24, lines 6-9 and 47-57 indicate that a controller is provided for regulating the operation of the light source. Bentsen, however, does not expressly disclose the use of a partitioning element.

Ukrainczyk discloses a fiber optic sensor capable of detecting the presence of analytes in a sample solution. Analytes and substrates are allowed to move through a membrane (Figure 8C:53) and form a biological product that is detected by a fiber optic sensor (Figure 8C:28).

Bentsen and Ukrainczyk are analogous art because they are from the same field of endeavor regarding enzyme detection through fluorescence.

At the time of the invention, it would have been obvious to provide the apparatus disclosed by Bentsen with an optical fiber probe comprising a partition element in order to detect fluorescence from the produced biological molecule. Ukrainczyk indicates that the use of partition elements is beneficial because partition elements are permeable to the enzyme

compound that is being detected, but impermeable to unwanted components in solution. This is desirable because it insures that all detected emission light is produced by enzyme-substrate biological molecules, and not by peripheral molecules.

The combination of Bentsen and Ukrainczyk still differs from Applicant's claimed invention because Ukrainczyk does not specifically disclose that the partitioning element allows partitioning of only one of the biological molecule and at least one substrate. Ukrainczyk's membrane allows the partition of the analyte, substrate and reaction product instead of partitioning only the substrate or product as required by the claims.

Applicant, however, has indicated on pages 17 and 18 of the specification that PDMS membranes capable of partitioning only a biological molecule or only a substrate thereinto are known in the art and are commercially available. Specifically, Applicant points to GE RTV118 manufactured by General Electric and Sylguard 186 and Sylguard 184 each manufactured by Dow (specification, page 17, lines 33-35).

At the time of the invention, it would have been obvious to provide the system in Bentsen with a partitioning element as disclosed by Ukrainczyk where the partitioning element is formed from a material well known and commercially available in the membrane art. Applicant has disclosed that PDMS membrane materials are easily acquired and implemented in fiber optic sensing systems. PDMS materials are additionally known in the art to be inexpensive, durable, biologically inert, and easily micro-machined. It would have been apparent to one of ordinary skill in the art to select known membrane materials through routine experimentation in order to obtain expected results.

With respect to claims 25 and 28, Bentsen, Ukrainczyk and Applicant's admitted prior art disclose the apparatus set forth in claim 24 as set forth in the 35 U.S.C. 103 rejection above. Additionally, Bentsen discloses in column 22, line 65 to column 23, line 5 and column 24, lines 7-9 and 47-57 that the apparatus is provided with control means for regulating the operation of the system, as well as control means for storing and outputting fluorescence data. A processor assembly (Figure 1:350) is provided for transmitting data electronically.

With respect to claims 29, 30 and 32, Bentsen, Ukrainczyk and Applicant's admitted prior art disclose the apparatus set forth in claim 24 as set forth in the 35 U.S.C. 103 rejection above. In addition, Bentsen discloses in column 17, lines 10-52 that the organism is *Escherichia coli*, and that the sample is selected from water, biological samples, food, and soil.

With respect to claims 31 and 33, Bentsen, Ukrainczyk and Applicant's admitted prior art disclose the apparatus set forth in claim 24 as set forth in the 35 U.S.C. 103 rejection above. Bentsen additionally indicates in column 16, lines 22-59 that beta glucuronidases and beta galactosidases are known in the art as enzymes that are used in the detection of microorganisms. Column 3, lines 14-16 and column 16, lines 22-59 indicate that glucuronides and galactopyranosides are known in the art as acceptable substrates.

With respect to claims 34 and 35, Bentsen, Ukrainczyk and Applicant's admitted prior art disclose the apparatus set forth in claim 24 as set forth in the 35 U.S.C. 103 rejection above. As previously noted, Bentsen discloses in column 22, line 56 to column 23, line 5 that the system

includes optical components (Figure 1:340) for monitoring fluorescence detection. Bentsen teaches that fluorogenic dyes are attached to the substrate, and incorporated into the biological molecule formed by the substrate-enzyme reaction. This is disclosed in column 10, lines 7-14.

2) Claims 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bentsen (US 6566508) in view of in view of Ukrainczyk (US 20040047535) and Applicant's admitted prior art as applied to claim 24, and further in view of Lee (US 20030222012).

Bentsen, Ukrainczyk and Applicant's admitted prior art disclose the apparatus set forth in claim 24 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose the use of a removable cartridge in the vessel that is capable of containing the sample and the substrate. Bentsen and Ukrainczyk do not disclose a removable cartridge containing a partitioning element.

Lee discloses a removable cartridge that comprises a mesoscale filter that is capable of partitioning cellular components in a sample. Detectable compounds are moved through the filter in an effort to remove undesirable cellular elements. The detectable compounds are then moved to a detector in order to verify their presence in the sample. This is disclosed in paragraphs [0008], [0012], [0016]-[0018] and [0045]-[0048]. Paragraph [0069] specifically states that the device is configured as a cartridge for easy insertion and removal from a vessel, and paragraph [0071] indicates that the device is used to biological microorganisms.

Bentsen, Ukrainczyk, Applicant's admitted prior art and Lee are analogous art because they are from the same field of endeavor regarding microorganism detection devices.

At the time of the invention, it would have been obvious to provide the apparatus disclosed by Bentsen and Ukrainczyk with a removable cartridge for containing the sample and partitioning biological molecule products. In paragraph [0069], Lee indicates that removable cartridges are beneficial because they can easily be moved from one reaction vessel to the next. Removable cartridges are known in the art to be reusable and therefore cost effective. Lee indicates in paragraphs [0012] and [0016]-[0018] that removable cartridges that employ partitioning membranes are especially beneficial because they represent a means by which biological molecules can be separated from undesirable cellular compounds that would otherwise interfere with accurate detection procedures.

Response to Arguments

Applicant's arguments filed 30 March 2007 with respect to the 35 U.S.C. 103 rejections involving the combination of Bentsen and Collins have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground of rejection is made in view of the combination of Bentsen with Ukrainczyk and Applicant's admitted prior art.

The Ukrainczyk reference addresses the deficiencies of Bentsen by indicating that it is known in the art to provide a partitioning element capable of isolating key components from other undesirable compounds in solution. Applicant's admitted prior art further indicates that PDMS materials capable of partitioning only a biological molecule product or only a substrate are known in the art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read "NAB", is written over the printed name "NAB".

NAB